



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,282	08/28/2001	Pravin Chaturvedi	VPI/01-119	8388

7590 02/10/2003

Andrew S. Marks, Esq.
VERTEX PHARMACEUTICALS INC.
130 Waverly Street
Cambridge, MA 02139-4242

[REDACTED] EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	6

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,282	CHATURVEDI ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 November 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 3 is/are allowed.

6) Claim(s) 1,2,4-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 18 November 2002 is acknowledged. Claims 1-12 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The objection to claims 8-12 is withdrawn in response to Applicant's amendment.
4. The rejection of claims 1-2, 5-9, and 12 under 35 U.S.C. 102(b) as anticipated by Wright et al. is withdrawn in response to Applicant's arguments that Wright et al. does not teach co-administration.
5. The rejection of claims 3, 4, and 5-12 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is withdrawn in response to Applicant's amendment.
6. The rejection of claims 8-12 under 35 U.S.C. 112, second paragraph, as indefinite due to multiple dependency is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained/New Grounds of Rejection

7. The rejection of claims 1, 2, and 5-10 under 35 U.S.C. 102(b) as anticipated by Glue is maintained for reasons of record in the office action of paper no. 3.

Applicant argues that Glue does not teach co-administration of ribavirin and interferon alpha. Applicant is referred to figure 7, p. 23, which shows co-administration of ribavirin and interferon alpha (solid bars).

Art Unit: 1646

8. The rejection of claims 1, 2, 5-9, and 12 under 35 U.S.C. 103(a) as unpatentable over Brunet et al. in view of Markland et al. is maintained for reasons of record in the office action of paper no. 3.

Applicant argues that Applicant's invention provides a method for determining an optimal dosage level. Applicant argues that Brunet teaches individual variability. Applicant states that a given dose will generate different C_{min} and C avg ratios. Applicant concludes that neither Brunet nor Markland suggest the optimal dosage of claim 1 or methods of treatment with such an optimal dose.

Applicant's arguments have been fully considered but have not been found to be persuasive. Claim 1 is drawn to a composition, and a composition is composition, regardless of how much of it is present in the bottle. Furthermore, a dose that is taught by the art is the same dose, regardless of how it is arrived at. Similarly, a method using that dose is the same method, regardless of how the dose is arrived at. That Applicant has evolved a different rationale for using a known composition at a known dose does not alter the composition, the dose, or the method of use.

9. Claims 1, 2, 5-9, and 11 are newly rejected under 35 U.S.C. 103(a) as unpatentable over Wright et al. in view of Markland et al.

Markland et al. teaches that ribavirin is used in combination with interferon alpha to treat hepatitis C (see abstract, p. 859). Markland et al. further teaches that ribavirin is an IMPDH inhibitor and that VX-497 is an IMPDH inhibitor that can be used similarly. See abstract, p. 859, p. 860, column 1, and figure 4, p. 865. Markland et al. fails to teach *in vivo* administration of VX-497 to treat hepatitis C and further fails to teach doses arrived at by Applicant's methods.

Art Unit: 1646

Wright et al. teaches treatment of hepatitis C with VX-497 and teaches levels exemplified by Applicant on p. 17 of the specification. Wright et al. fails to teach coadministration with interferon alpha. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Wright et al. with those of Markland et al. to administer VX-497 in combination with interferon alpha to treat hepatitis C virus. One of ordinary skill would be motivated to do so because Markland et al. teaches that the IMPDH inhibitor ribavirin can be used with interferon alpha to treat hepatitis C and teaches that VX-497 functions similarly to ribavirin, and Wright et al. teaches *in vivo* doses to treat this same disease. Thus one of ordinary skill in the art expect VX-497 to be useful in combination with interferon alpha to treat hepatitis C, and would expect the doses taught by Wright et al. to be appropriate for such treatment.

10. Claims 1, 2, and 4-12 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "alpha interferon or a derivative". While interferon alpha is well known in the art, it is not clear that the metes and bounds of alpha interferon derivatives are as well understood, and Applicant has not set forth the characteristics of a "derivative" so that one of skill in the art would be able to determine what molecules are included.

11. Claim 4 is newly rejected under 35 U.S.C. 112, second paragraph, as indefinite because, while the claim is drawn to a method of producing a composition, the method steps describe a method of determining an optimal dosage.

CLAIM 3 IS ALLOWED. CLAIMS 1, 2, AND 4-12 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
February 4, 2003


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600